

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 30 December 2009, is acknowledged. Claims 1, 11, 13, 15, 17, 29, 48, 56, 57 and 59 have been amended.
2. Claims 1, 2, 4-6, 8-11, 13, 15-17, 29-31 and 48-61 are pending and under consideration.

### **Rejections Maintained**

3. The rejection of claims 1, 2, 4-6, 8-11, 13, 15-17, 29-31 and 48-61 under 35 U.S.C. 112, first paragraph, scope of enablement for differentiation of any/all forms of TSE by mere alteration of level of nonspecified proteins, is maintained.

Applicants argue that the claims are drawn to diagnosis of a TSE selected from the group consisting of BSE, vCJD and CJD, not all forms of TSE.

The examiner has considered applicants' argument, but does not find it persuasive. While the newly amended claims may be drawn to BSE, vCJD and CJD, the claims also are drawn to diagnosis based upon one nonspecified protein chosen from a list of proteins with molecular weights "within 1%" of a listed molecular weight, and the only distinguishing criteria is that the level of the protein be different from that of non TSE individuals. However, neither the specification nor the claims state what is to be considered a significant difference.

4. Claims 1, 2, 4-6, 8-11, 13, 15-17, 29-31 and 48-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for detection of levels of proteins distinguishing TSE from other diseased states, is maintained.

Applicants argue that the lowest mass given in the referenced patent (U.S. Pat. No. 6,416,962) is 10 kDa (10,000 Da) and that it is unlikely that one skilled in the art of mass spectrometry would consider the majority of the claimed molecular weights to be "within 1%"

of 10 kDa, because 27 of the 29 polypeptides claimed are more than 10% different in mass. Applicants state that the specification clearly defines in paragraph (0059) that the term "about".

The examiner has considered applicants' argument, but does not find it persuasive because the claims are drawn to a diagnosis based upon "a polypeptide selected from a group" of polypeptides, i.e., based upon one polypeptide which is "within 1%" a stated molecular weight. Applicants state that support for said amendment is found in paragraph 0059 of the published version of the specification. However, the actual paragraph, 0050, states:

Measurement of the molecular weight of the polypeptide or polypeptides is effected in the mass spectrometer. All molecular weights herein are measured in Da. The molecular weights quoted above can be measured with an accuracy of better than 1%, generally 0.5 to 1%, and preferably to within about 0.1%. The term "about" in connection with molecular weights in this specification therefore means within a variation of about 1%, preferably 0.5%, and more preferably within about 0.1%, above or below the quoted value.

The 10,000 Da protein which is diagnostic for *M. tuberculosis* fits within the 1% variation of at least one of the claimed listed polypeptides. The specification does not define how one distinguishes between tuberculosis and TSE. The rejection is maintained.

### Conclusion

5. No claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 31, 2010